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09/995,010	11/27/2001	Stanislaw R. Burzynski	BURG:04910379.0049.NPUS00	9045

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EXAMINER
JONES, DWAYNE C

ART UNIT	PAPER NUMBER
1614	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/995,010	Applicant(s) BURZYNSKI, STANISLAW R.	
	Examin r Dwayn C Jones	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-31 are pending.

2. Claims 1-31 are rejected.

Response to Arguments

3. Applicant's arguments filed January 13, 2003 have been fully considered but they are not persuasive. Applicant makes the following arguments. First, applicant argues that Schmidl et al. and Acosta et al. are directed to nutritional compositions containing a broad spectrum of amino acids and vitamins. Applicant argues that Schmidl et al. is directed to a nutritional support to individuals who are unable to orally consume/digest food because of gastrointestinal conditions, such as inflammatory bowel disease, intractable diarrhea, as well as other ailments. Next, applicant alleges that neither Schmidl et al. nor Acosta et al. teach or suggest methods/compositions for reducing the toxicity of chemotherapy. Applicant also alleges that it is evidenced in the art, namely Koretz that providing additional nutrition using compositions such as those of Schmidl et al. and Acosta et al. is minimally beneficial to cancer patients undergoing chemotherapy and could cause harm. Applicant also argues that glutamine is an essential metabolic substrate for tumor growth. Applicant further argues that the folic acid of Schmidl et al. and Acosta et al. stimulates cancer growth.

4. Applicant first argues that Schmidl et al. and Acosta et al. are directed to nutritional compositions containing a broad spectrum of amino acids and vitamins.

Schmidl et al. teach of a dietary composition that is useful to provide nutrients, vitamins, and minerals to individuals in need thereof. Applicants argue that Schmidl et al. teach of a broad dietary composition. However, the prior art reference of Schmidl et al. teach of a "most preferred composition", which specifically contains L-alanine, glycine, L-serine, taurine, L-threonine, and L-valine as well as L-arginine and riboflavin. In addition, it would have been obvious to the skilled artisan to utilize the compounds that are instantly claimed in a composition that is consists of contains L-alanine, glycine, L-serine, taurine, L-threonine, and L-valine as well as an effector of the urea cycle and riboflavin in view of the fact that Schmidl et al. teach of the "most preferred composition", (see column 5). Acosta et al. disclose of a nutritional product that are comprised of a mixture of the amino acids of L-alanine, L-serine, glycine, L-threonine, L-Valine, taurine, riboflavin as well as L-arginine, (see Tables 1 and 3). Acosta et al. teach of utilizing their composition enterally to individuals in need thereof. Despite the fact that Acosta et al. use their composition to treat metabolic disorders, the composition of Acosta et al. do teach of a pharmaceutical composition that renders the instant composition and method claims because Acosta et al. provide one having ordinary skill in the art with the motivation to employ these compositions to individuals in need of these nutrients and vitamins, especially those individuals who receive these nutrients and vitamins enterally, as may be in the case of patients undergoing cancer chemotherapy.

5. Moreover, instant independent claims 1 and 26 are directed to open-claim language. Applicant recites the word "comprising", which is open-claim language. It is

held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

6. Applicant argues that Schmidl et al. is directed to a nutritional support to individuals who are unable to orally consume/digest food because of gastrointestinal conditions, such as inflammatory bowel disease, intractable diarrhea, as well as other ailments. The diseases of Schmidl et al. are only illustrative, (see column 1, lines 29-35). The Schmidl et al. invention, however, is directed to administering a dietary composition that contains the instantly claimed nutrients and vitamins to provide proper nutrition to individuals, especially those who are undergoing certain conditions or diseases and who are unable to consume food orally and thus must be fed enterally, (column 1, lines 8, 9, 18-42). Accordingly, it would have been obvious to one having ordinary skill in the art to use these well-known amino acids and vitamins to treat individuals from a variety of conditions or ailments where the individual in need thereof has a reduced dietary intake, which can be due to a variety of reasons, including cancer as well as cancer chemotherapy.

7. Next, applicant alleges that neither Schmidl et al. nor Acosta et al. teach or suggest methods/compositions for reducing the toxicity of chemotherapy. Schmidl et al. teach of a "most preferred composition" that is useful for providing nutrients to individuals with diseases, especially those who are unable to consume food orally and must be fed enterally, (see column 1). This would obviously include patients undergoing cancer chemotherapy. Consequently, the skilled artisan would have been

motivated to use the disclosure of Schmidl et al. to help treat individuals who suffer from malnutrition because Schmidl et al. specifically teach that the "most preferred composition" is administered to individuals with diseases, especially those who are unable to consume food orally and must be fed enterally. Even thought the invention disclosed by Acosta et al. is directed to administering a dietary composition that contains the instantly claimed nutrients and vitamins to provide proper nutrition to individuals, especially those who are undergoing certain conditions or diseases and who are unable to consume food orally and thus must be fed enterally, (see Tables 1 and 3). It would have been obvious to the skilled artisan to use these well-known amino acids and vitamins to treat individuals from a variety of conditions or ailments where the individual in need thereof has a reduced dietary intake, which can be due to a variety of reasons, including cancer as well as cancer chemotherapy.

8. Applicant also alleges that it is evidenced in the art, namely Koretz, that providing additional nutrition using compositions such as those of Schmidl et al. and Acosta et al. is minimally beneficial to cancer patients undergoing chemotherapy and could cause harm. Applicant alleges that it is known in the art that providing additional nutrition, such as that of Schmidl et al. and Acosta et al., is minimally beneficial and can cause harm. The following cites are noted from Koretz. First, Koretz teaches that "parenteral nutrition does appear to reverse parameters of malnutrition". (as cited from page 534, column 1, 3rd paragraph). Koretz also teach that parenteral nutrition makes it possible to provide nutrition, via intravenous route, to any patient who cannot or will not eat, (see page 534, column 1, 2nd paragraph). Koretz also disclose that nutritional support might

improve host defense, and so one might expect a better response to various chemotherapeutic modalities, (see page 535, column 1, paragraph 1). Koretz conclude that most of the studies reviewed only had "small numbers of patients; marginal benefits afforded by PN could be missed in the statistical analysis. Koretz even states that, "[I]mplicit in this argument, however, is the acceptance of the concept that at best PN will only provide small benefits", (as cited from page 537, column 2, 3rd full paragraph). Obviously, any form of a benefit to a patient or individual in need thereof would be good and thus provide the skilled artisan with motivation to use the administration of well-known amino acids and vitamins.

9. Applicant also argues that glutamine is an essential metabolic substrate for tumor growth. The prior art reference Chance et al. only teach that glutamine *can* inhibit the growth of *transplantable* sarcomas. For these reasons, this prior art reference may only be applicable to transplantable sarcomas. The fact that Schmidl et al. and Acosta et al. include this amino acid does necessarily dissuade the skilled artisan from utilizing these prior art compositions to treat patients with a composition of needed amino acids and vitamins.

10. Applicant further argues that the folic acid of Schmidl et al. and Acosta et al. stimulates cancer growth. Synold et al. only suggest that there is a need for clinical trials that incorporate new strategies with known active antimetabolites. In fact, Synold et al. state that there should be further laboratory and clinical investigations with folypolyglutamate synthetase, (see abstract). The skilled artisan would require further studies with this enzyme in order to arrive at applicant's allegation.

Information Disclosure Statement

11. The information disclosure statements filed on January 13, 2003 and April 15, 2003 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

12. It is also requested that applicant place the reference of Koretz on a PTO FORM 1449 so that they may be listed properly.

Claim Rejections - 35 USC § 103

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. The rejection of claims 1-31 are under 35 U.S.C. 103(a) as being unpatentable over Schmidl et al. of U.S. Patent No. 5,719,134 is maintained and repeated for both the above-stated and reasons of record. Schmidl et al. teach of a dietary composition useful for providing nutrition to individuals with diseases, especially individuals who are unable to consume food orally and must be fed enterally, (see column 1). Schmidl et al. teach a preferred composition which contains L-arginine, L-alanine, glycine, L-serine, taurine, L-threonine, L-valine, and riboflavin, (see column 4, line 21 to column 5, line 12). The instant claimed pharmaceutical claims are in fact pharmaceutical claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S 327, 65 USPQ 297 (1945). In addition, Schmidl et al. do teach one having ordinary skill in the art that these claims are pharmaceutical

claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease, (see column 1, lines 28-30 and lines 37-67). Accordingly, it would have been obvious to the skilled artisan to utilize this nutritional composition of Schmidl et al. to treat a variety individuals, who suffer from malnutrition due to a disease or condition which causes or is associated with the malnutrition.

15. The rejection of claims 1-31 under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. of U.S. Patent No. 5,550,146 is maintained for above-stated and reasons of record. Acosta et al. disclose of a nutritional composition, which contains vitamins and amino acids, for the treatment of various metabolic diseases, (see abstract and columns 1 and 2). In fact, Acosta et al. specifically recite the following constituents of taurine and riboflavin, (as cited from Table 1, column 17) and L-alanine, L-arginine, glycine, L-serine, L-threonine and L-valine, (as listed in Table 3, column 21). The instant claimed pharmaceutical claims are in fact pharmaceutical claims with an intended use of treating or reducing the effects of malnutrition associated with a condition or disease. The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S 327, 65 USPQ 297 (1945). Even though the prior art reference of Acosta et al. is directed to treating inherited metabolic disorders, the compositions of Acosta et al. do teach of pharmaceutical compositions which render the instant invention obvious. In addition, because Acosta et al. do teach that the administration of these nutritional compositions are used to treat metabolic disorders, the skilled artisan would have been motivated to utilize the compositions of Acosta et al.

to treat other diseases, ailments or conditions where metabolic disorders are treatable with the administration of dietary, nutritional compositions. Accordingly, it would have been obvious to one having ordinary skill in the art to utilize the nutritional compositions of Acosta et al. to treat metabolic disorders caused by a variety of diseases or conditions, such as cancer.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
May 14, 2003